REMARKS

Interview Summary

Applicant's attorney wishes to thank the examiner for the courtesies extended during the personal interview of October 20, 2011. The independent claims 112 and 113 were discussed in relation to the prior art Ober (US 4,669,477) reference. The inclusion of a calculation of a threshold value in the pending claims was described as distinguishing over the prior art that discloses a dial to manually adjust a threshold value. The examiner pointed to language in the claims that may be indefinite and requested correction.

Status

Claims 85-111 were pending in the present Office Action. By this response, claims 85 and 109-111 were canceled, and new claims 112-114 were amended. Accordingly, it is now claims 86-108 and 112-114, as amended, which are at issue.

The Office Action

In the Office Action mailed May 31, 2011, claims 85-111, all claims then pending, were rejected. Specifically, claims 85-93, 99, 102-104 and 109-111 were rejected under 35 U.S.C. §103 as being unpatentable over U.S. Patent 4,669,477 of Ober taken in view of the publication of Lavigne, of record. Claims 94, 95 and 97 were rejected under 35 U.S.C. §103 over the combination of Ober and Lavigne taken further in view of U.S. Patent 6,270,466 of Weinstein. Claim 96 was rejected under 35 U.S.C. §103 over the combination of Ober and Lavigne taken further in view of U.S. Patent 5,368,043 of Sunouchi. Claims 98, 101, 105 and 106 were rejected under 35 U.S.C. §103 over the combination of Ober and Lavigne taken further in view of U.S. Patent Application Publication 2004/0068196 of Massicotte. Claim 100 was rejected under 35 U.S.C. §103 as being unpatentable over the combination of Ober and Lavigne taken

further in view of U.S. Patent 6,306,100 of Prass. Claims 107 and 108 were rejected under 35 U.S.C. §103 as being unpatentable over the combination of Ober, Lavigne, and Massicotte taken further in view of U.S. Patent 5,877,444 of Hine.

In addition, claims 106-108 were rejected under 35 U.S.C. §112, second paragraph.

The Presently Claimed Invention

The invention as presently claimed is directed to systems and a method which operate in real time, with regard to a sleeping patient, to detect the onset of bruxism and provide a feedback signal to the patient which enables the patient to control the condition. Various alarm systems for managing bruxism are known in the art, such as the Ober prior art presently of record. However, the system of the present invention differs from those of the prior art in a very significant way insofar as the system of the present invention operates to determine a threshold level by a calculating step of jaw activity which is unique to that particular patient and which corresponds to the onset of bruxism. The prior art does not include any type of system which automatically determines or calculates a patient-unique threshold level of jaw activity indicative of bruxism. As already detailed in the record of the prosecution of this application, the prior art systems such as those of Ober require a user to arbitrarily and manually select a threshold level of jaw activity which is used to trigger a warning signal. This level of activity is selected without regard to any specific parameters, may or may not accurately reflect the occurrence of bruxism, and is essentially a "trial and error" method that involves no calculation of a threshold.

The system of the present invention utilizes a three-step process to determine a patient-unique threshold level which accurately indicates bruxism. As detailed in the claims, the system of the present invention:

(1)   measures a first level of muscular activity of a user's jaw associated with a level of biting force and generates a first signal corresponding thereto;

(2)   measures a second level of muscular activity of a user's jaw associated with normally occurring non-biting jaw activity and generates a second signal corresponding thereto; and

(3)   processes the first and second signals to calculate a threshold level of muscular activity which is less than 100% of the first level of muscular activity but more than a second level of muscular activity.

A threshold level determined by this three-step process will be unique to each patient and will accurately reflect the onset of bruxism activity. Determination of the threshold by the three-step process is to be contrasted with the simple trial and error setting of a threshold in the prior art insofar as the prior art does not measure the first and second levels of jaw activity at all and hence does not provide any type of signal which is unique to a particular patient. As such, the present invention involves particular steps neither shown nor suggested in the prior art.

The Rejections

All pending claims stand rejected as being obvious in view of the base combination of Ober and Lavigne, further supplemented with secondary references in regard to certain of the dependent claims. Applicant respectfully submits that neither the Ober nor Lavigne references taken either singly or in combination show or suggest the system and/or method of the present invention. Applicant notes, for the record, that these references have been extensively discussed in the prior prosecution of this application, and all of such remarks are incorporated herein by reference.

As mentioned above, Ober is atypical of prior art systems used in an attempt to control bruxism and, as such, employs a manually set sensitivity threshold. The Examiner, in the response to Applicant's arguments at page 10 of the present Office Action, states that:

> Ober does not explicitly or inherently disclose the claimed threshold determination steps, but does disclose the ability to manually set a threshold.

The Examiner states that:

> the replacement of a manual determination of a threshold with an automatic determination is a design consideration to one of ordinary skill in the art.

The Examiner holds that it would be thus obvious to look to the teaching of Lavigne for the automation of the Ober threshold determination.

Applicant agrees with the Examiner that the mere automation of a step which was previously implemented manually is per se obvious. However, Applicant points out to the Examiner that the present invention does not merely represent the automation of the threshold setting in Ober. The Ober prior art in no way provides any guidance to a user as to where the threshold sensitivity of the bruxism control apparatus is to be set. The sole teaching in Ober is that a user must arbitrarily select some sensitivity value, and there is no teaching provided as to what parameters define this value. The essence of the present invention is that an accurate and unique threshold is determined and calculated (**irrespective of any issue of automation**) by the three-step process set forth above. Ober provides no teaching showing or suggesting this three-step process including a calculation of a threshold in either a manual or automated method.

Applicant points out to the Examiner that **method claim 113 does not include any steps of automation** but claims the method steps of the present invention as used for determining a threshold of muscular activity indicating the onset of bruxism. Included in the three steps is the

calculation of a threshold. This process could be implemented in a manual method or in an automated method. As acknowledged by the Examiner, for example in the passage quoted above, Ober does not show or suggest this three-step threshold determination process. As such, method claims 113, as well as claim 114 dependent therefrom, is novel and nonobvious.

The apparatus claims are similarly allowable. Applicant concedes that if Lavigne showed Applicant's three-step process for determining a patient-unique threshold level of jaw muscle activity indicative of bruxism, mere automation of the implementation of that method would not be patentable. However, as acknowledged by the Examiner, this three-step process is nowhere shown or suggested in Lavigne. Hence, an apparatus which operates to implement that three-step process (in an automated or non-automated manner) is likewise novel and nonobvious. Claim 112 specifically includes a sensor system that calculates a threshold. No such structure is taught or suggested in the prior art.

The Lavigne publication, taken either singly or in combination with Ober, does not provide any support for the rejection of the presently amended claims. Lavigne is directed to a system for collecting and analyzing data related to bruxism. As such, it is an analytical tool used to evaluate previously collected data to determine if a subject may have undergone episodes of bruxism. The method of Lavigne does not correspond to Applicant's three-step process. Furthermore, it is not implemented on any real-time basis in connection with a sleeping patient and as such cannot be utilized as the basis for any biofeedback-based device or method for conditioning a patient to avoid episodes of bruxism.

The Lavigne method does analyze various bite data collected from patients during sleep and wakefulness; however, the **analysis of the data is not carried out while the patient is**

asleep. Hence, Lavigne cannot provide any immediate feedback signal to a patient which would condition the patient to avoid the initiation of bruxism.

The overall teaching in Lavigne is of methods for calibrating data collection systems and not to determination of threshold levels using a calculation step for the onset of bruxism in a sleeping patient. As particularly detailed on page 547 of Lavigne, a patient carries out five distinct tasks so as to produce a specific EMG signal. As stated in Lavigne, the purpose of doing so is to obtain patient-specific recordings of these particular jaw movements so as to be able to recognize these same movements when carrying out later analyses of sleep-collected data. All analysis in Lavigne is carried out **after sleep measurements are made and hence while the patient is awake.** There is no real-time analysis or assessment of data recorded during sleep and hence there can be no implementation or suggestion of Applicant's three-step process.

As acknowledged in Lavigne, electrical activity of the jaw muscles is weak and hence must be amplified for further processing. Lavigne recognizes that if this amplification is too strong the signal may be saturated and difficult to analyze. Hence, Lavigne proposes a method for calibrating and adjusting EMG signal measurement in acquisition apparatus so as to avoid signal saturation.

Lavigne makes clear from the discussion at pages 550 and 551 that the study does not actually provide any clear-cut diagnosis of bruxism. What Lavigne does is provide cutoff criteria which is used as one factor among a plurality of interrelated parameters and criteria used in the diagnosis of bruxism. As noted at page 550, right column, of Lavigne, "Cutoff values do not give a simple yes or no outcome. The cutoffs are not absolute numbers and they should not be used without the overall patient evaluation." As such, Lavigne is clearly directed to a system for accurately collecting data relating to EMG signals generated by a patient's jaw muscles. It is

not directed to a system which operates in real time to identify the onset of bruxism and provide a sleeping patient with a biofeedback-based control signal.

In making the rejection of the claims the Examiner acknowledges that the Ober patent does not disclose any system which carries out Applicant's claimed three-step process; however, the Examiner contends that these specific steps are taught by Lavigne and would thus be obvious. As discussed above, in view of the present amendments to the claims, this rejection is overcome. Lavigne does not explicitly or implicitly disclose any system which operates in a real-time feedback mode to control bruxism, but merely provides a system for collecting data which is used as part of an "overall patient evaluation" in diagnosing bruxism. Lavigne does not show any system operative in real time to provide an immediate feedback signal to a sleeping patient which ends an episode of bruxism. Given the purpose and operation of the Lavigne system, it is clear that there is no incentive to look to the teaching of Lavigne for any guidance as to systems for controlling bruxism and there would be no expectation that adding any steps from Lavigne to a method or process of Ober would achieve the benefits of the present invention. In view thereof, Applicant respectfully submits that all rejections based upon the combination of Ober and Lavigne are overcome by these remarks and amendments.

Various of the dependent claims have been rejected on the basis of Ober and Lavigne taken further in view of secondary references. These rejections are likewise overcome in view of the inapplicability of the base reference.

The Rejections under 35 U.S.C. §112, Second Paragraph

Claims 106-108 were rejected under 35 U.S.C. §112, second paragraph, as being indefinite with regard to language the Examiner has interpreted as reciting method steps.

Applicant thanks the Examiner for pointing out this lack of clarity and has amended these claims

accordingly. This rejection is now overcome.

Conclusion

In view of the foregoing amendments and remarks, Applicant respectfully submits that all

objections and rejections are overcome and the application is in condition for allowance. Should

the Examiner have any questions or comments which would place the application in still better

condition for allowance, he is respectfully requested to contact the undersigned attorney.

The Director is hereby authorized to charge any deficiency in the fees filed, asserted to be

filed or which should have been filed herewith (or with any paper hereafter filed in this

application by this firm) to our Deposit Account No. 07-1180.

Dated: October 26, 2011   Respectfully submitted,

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